Fax Cover Sheet

kinko's

1194 El Camino Real
Menlo Park, CA 94025
Tel: (650) 321-4202
Fax: (650)321-1387

Date: 3-15-02

To: Stephen Kunin, Deputy Comm. for Patent Examination Policy

Company: U.S. Patent & Trademark Office

Fax: 703-305-8825

From: NANCY McKINNEY

~~Company~~: Regarding a recent CIP

Tel: daytime M-F: 650 424-8222 X 4655
Home 650 747 0273

Number of pages including this one: _____

Comments:

This is an urgent matter.

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Nancy McKinney
P.O. Box 706
La Honda, CA 94020
Nmckinney@prodigy.net
(650) 747-0273

3 March, 2002

Stephen Kunin,
Deputy Commissioner for Patent Examination Policy,
United States Patent and Trademark Office,
Fax: 703-305-8825
RE: CIP filed by Ken Weber of Townsend and Townsend on the part of Lawrence Berkeley National Lab (LBNL), which modifies Provisional Patent serial no. 60/138/167(filed 6-8-99), and Patent serial no. 09/590/759 filed 6-8-2000, (but only by addition of gratuitous inventors).

Dear Sir,

I am the inventor named on both filings listed above. This letter concerns the CIP, it's probable intent, and the procedures employed to institute it.

I refused to sign the CIP, as did the Principle Investigator of the DOE funded project under which the discovery being patented was made, Dr. J.C. Hunter-Cevera. I have included the letter that accompanied Dr. Hunter-Cevera's refusal to sign the CIP as it corroborates the facts I present herein.

The details of the various disputes surrounding this IP are somewhat sordid. I will try to steer clear of these details and review the facts as concisely and 'dispassionately' as I can. However, should you want more information don't hesitate to contact me.

1) I was encouraged to file an Invention Disclosure at LBNL for some very useful and potentially valuable work by both my direct manager (Dr. Hunter-Cevera) and the Director of the LBNL Life Science Division (Dr. Mina Bissell).
2) The above named managers were concerned that LBNL would lose the IP to a former collaborator of Dr. Hunter-Cevera, U.C. Berkeley professor Dr. Terrance Leighton.
3) Dr. Terrance Leighton is being investigated for Scientific Misconduct by UCB at the behest of a funding sponsor (the Office of Naval Research). The reasons for the Investigation are numerous and involve this IP, but constitute some of the sordid matters I choose to not detail.
4) I was asked by my managers to *help* write the Provisional Patent at LBNL. In fact, I ***wrote all but following parts***: the Background, the formal statement of Claims, and Example 11 in the Preferred Embodiment –which was 'cut and pasted' by the LBNL Patent Attorney (Dave Aston) from another document. I wrote the remainder of the Preferred Embodiment (the majority of the document) because the LBNL Patent Office did not know enough about the technology to do so, and, I am, in fact, an expert in PCR technology (see my attached C.V.).

5) My manager (Dr. Hunter-Cevera) had insisted that the Provisional be filed naming me as sole inventor, since it described my work and I wrote most of it. Following the filing of the Provisional Patent an Investigation of Inventorship was conducted by Dave Aston, the LBNL Patent Attorney, prior to filing for the 'Full' Patent. NOTE that Inventorship remained unchanged following this Investigation –I alone was named Inventor.
6) Soon after the 'Full' Patent was filed by LBNL, Dr. Leighton hired an attorney, Peter Sandmann, to contact LBNL demanding that I be investigated for Scientific Misconduct for being named sole inventor of this IP.
7) I was, in fact, investigated for this charge; this entailed *another* Inventorship Investigation. I have included, following this letter, the findings of the independent committee of LBNL scientists appointed to investigate this matter. To summarize, they found "no evidence that Ms. McKinney intentionally misrepresented or fabricated her efforts to apply for sole inventorship of the case in question. Hence, no scientific misconduct could be identified".
8) The Scientific Misconduct Investigation of Dr. Terrance Leighton was reconvened. Dr. Hunter-Cevera, currently President of the University of Maryland Biotechnology Institute, was informed by Dr. Robert Price who is coordinating the reinvestigation at UCB, that there was a good deal of pressure for the University to drop the investigation of Dr. Leighton.
8) In December 2001 I was contacted by Ken Weber of Townsend and Townsend and Crew, who, according to Dave Aston, had been retained to prepare a patent purported to be *broader* than the one naming me as Inventor. Ken Weber told me he was investigating inventorship for this 'new' patent. I told him the history of the IP discovery. It differed from what he heard from Dr. Leighton. Among the differences was that Dr. Leighton claimed to be P.I. of the project, which he was ***not*** for the period covering the discovery. I informed Mr. Weber that Dr. Leighton did not contribute <u>in any way</u> to the discovery on which the IP in question is based. In fact, Dr. Leighton attempted to ***interfere with*** the work which lead to the discovery by insisting on different course of research based upon his own theories. Once my approach proved fruitful, he claimed to the scientific community (and funding agencies) that the discovery was made in HIS lab at HIS bidding.

   I told Ken Weber about the Scientific Misconduct investigation and my concern that (wrongly) naming Dr. Leighton as a discover of this IP would be used to exonerate him of wrongdoing. He said that was none of his business. He also said that the entire group would be named as Inventors on this new, broader, patent –***regardless*** of contribution, and . I reminded him that Dr. Leighton was not actually an official member of the LBNL group at the time of the discovery, but an invited guest and collaborator of the P.I. (Dr. Hunter-Cevera). I also reminded him that Dr. Leighton not only did <u>not</u> contribute to the discovery, but actually attempted to interfere with it –which Ken Weber found amusing. His response was that if he was in the room during <u>any</u> of our group meetings then he would be named as inventor, a "gratuitous" inventor (his pronoun).

9) Ken Weber had the 'new' patent delivered to me for review and signature on 12-24-01. I was shocked to discover that it was, in fact, virtually ***identical*** to Provisional Patent serial no. 60/138/167and Patent serial no. 09/590/759! The only difference I could find was one additional claim, which actually is a statement of known biological fact (nearly the entire <u>B.anthracis</u> *genome* has greater than 90% homology with the <u>B. cereus</u> genome!).

This is, of course, not a new patent, and the main thing 'broadened' is the list of Inventors -- despite TWO previous Investigations into Inventorship, each of which agreed that the "operable" work covered by this patent (PCR assay) was mine. I stress the term "operable" for the following reason: The original provisional patent (60/138,167 filed on June 8, 1999), though largely my own text, contains a section (example 11) which "teaches" the development of monoclonal antibodies –as though this could be accomplished against the saspB protein. This section was included against my wishes as sole inventor since David Aston (the LBNL Patent Attorney) was of the general opinion that the section *should* be there. I presented him with the long published and known scientific fact that the sasp-B protein resides in the center of the *Bacillus* spore and functions as a 'storage protein' whose 'job' is to fall apart into component amino acids immediately upon entry of the first water molecules into the spore. Hence, the sasp-B protein could *never* serve productively as the target of an antibody test. This claim has never been reduced to practice and never will be.

I noted also that someone used the term "cloned" in claims 1 and 19 of the "new" patent without "teaching" how this was accomplished. It is not a routine matter to clone Bacillus genes. I tried to clone the *B. anthracis* sasp-B gene prior to departing LBNL. *Bacillus* proteins are toxic to the commonly used *E. coli* bacterial hosts used in cloning. I was able to obtain most of the DNA sequence of this gene (all of the 'coding' sequence) by PCR, but I never actually cloned the gene. If someone else did this, the procedure (and some data) should have been included in this "new" patent/CIP!

So of the three types of claims in this "new" patent/CIP, a clone, an antibody, and PCR assays the only valid ones are the PCR assays. And the PCR assays are definitely my invention, a fact which has been repeatedly concluded in inventorship investigations.

So who benefits from this CIP? Mainly Dr. Leighton: If the CIP is allowed he can state, using this patent as evidence, that he 'discovered' the IP, and therefore is innocent of charges that he stole credit for the discovery (as well as data, documents, funding etc). This might come in handy in defense against the Scientific Misconduct charge. And the University of California also stands to benefit, since Dr. Leighton is absolutely the sort of person who would delight in suing the University if they find him guilty of Scientific Misconduct. It would be so much simpler for them to simply see him installed as inventor. Beyond that, Dr. Hunter-Cevera does not want to be named as an inventor, even 'gratuitously'; Dr. Longchamp fully admits to everyone that he had absolutely nothing to do with the discovery, reduction to practice, and testing of the invention. And while Dr. Goldman worked with me very briefly during the initial primer design he, along with Dr. Leighton, dismissed species specific PCR primer design directed to the sasp-B gene as IMPOSSIBLE, and did not participate in this development. However, of all the people currently named as inventors on this CIP he would be the only one, besides myself, with even the slightest reason to be there.

When I asked who Ken Weber was ***actually*** representing (it was rhetorical question), Dave Aston sent me a copy of the Patent assignment form I was required to sign at the time Patent serial no. 09/590/759 was submitted. This document was his answer to the question about

who Ken Weber represented: The University of California, Dr. Leighton's employer (and 'managing entity' of LBNL). This is why I speculated in the above paragraph about UC potentially benefiting from seeing Dr. Leighton named an Inventor on this patent. It solves many problems for them to claim that an 'independent and impartial' party (Ken Weber) investigated inventorship and determined that Dr. Leighton was deserving of it.

I am obviously not an attorney. I am a scientist, and although I've been a successful one for nearly 20 years, I still cannot afford to hire a patent law attorney (we scientist get paid largely in 'glory', which attorneys don't accept for payment). Yet even without the benefit of legal expertise it seems to me that it is wrong to use patents and inventorship in the manner I've described. If you look up the CIP you will now find that Dr. Leighton is listed beneath Dr. Hunter-Cevera as though he were a P.I. along with her, with the rest of Dr. Hunter-Cevera's original LBNL group listed in alphabetical order below him. The entire Scientific Misconduct case against Dr. Leighton has boiled down to the following dispute: he claims he was a P.I. of the project when the IP discovery was made (and this justifies everything he did thereafter), but he was NOT. And his employer, the University of California, who is supposed to be Investigating him for the funding sponsor (ONR), paid a LOT of money to hire the most powerful Patent Law firm on the West Coast to install him not only as inventor of this IP, but as what appears to be (due to the *priority* of inventorship) a P.I.

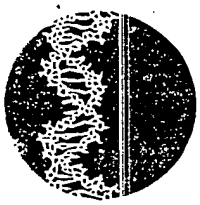
This doesn't seem **right** and I don't think the USPTO should allow this CIP. In fact, I would rather see the USPTO disallow the entire patent and lose credit as an inventor than see this patent of my invention(s) used this way!

Sincerely and Truthfully,

Nancy McKinney

Nancy McKinney, Research Scientist

Attached: Letter of refusal to sign CIP from P.I. Dr. Hunter-Cevera; Letter stating that Dr. Leighton accused me of Scientific Misconduct for being named sole inventor; Letters stating that I was found innocent of Dr. Leighton's charge; my C.V.; and a copy of an LBNL Tech Transfer web page.



UMBI
UNIVERSITY OF MARYLAND
BIOTECHNOLOGY INSTITUTE

COLUMBUS CENTER
701 EAST PRATT STREET, SUITE 200
BALTIMORE, MARYLAND 21202-3101
410.385.6305 TEL.
410.385.6312 FAX
WWW.UMBI.UMD.EDU

UMBI HEADQUARTERS
9600 GUDELSKY DRIVE
ROCKVILLE, MARYLAND 20850
301.738.6272 TEL.
301.738.6255 FAX

January 16, 2002

Mr. Kenneth Weber
Partner
Townsend and Townsend and Crew
Two Embarcadero Center
8th Floor
San Francisco, CA 94111-3834

Dear Mr. Weber:

This letter is in response to your letter dated December 20, 2001 requesting my signature for the declaration (37CFR 1.63) to file a continuation to Ms. McKinney's original patent application (09/590,759). I am not signing the declaration. I feel there is a problem with the inventorship of the application.

I see no additional new claims or differences in content of claims between the parent application and this CIP. Words were added for clarification perhaps, but essentially the CIP appears to be the same application as filed by LBNL with Nancy McKinney as sole inventor. In fact, I have concerns that the claims might be subject to a double patenting rejection.

There was an LBNL/UCB inventorship investigation during the fall of 2000 as to the inventor(s) for the claims originally filed and it was determined that Nancy McKinney was the sole inventor. While employed by LBNL as Head of the Center for Environmental Biotechnology, and as the original sole PI on the Department of Energy grant award which enabled this group to come together, I organized weekly meetings to review the data obtained based on the assignments within the group consisting of Stan Goldman, Pascal Longchamp, and Nancy McKinney. I invited Terry Leighton to attend as a potential collaborator. I feel I have a very good recollection of who did what and I do not believe that any other member of the group contributed to the primer-probe (PCR) diagnostic assay for *Bacillus anthracis*, *B. globigii*, and *Clostridium perfringens* as described in the original parent patent filing with Nancy McKinney as sole inventor.

You see, the major goal of the group from the outset was to discover a spore coat protein specific to *B. anthracis*, which was my original proposal funded by DOE. PCR was employed only as a quick means to find such a protein. Prior to bringing in Nancy, no one in the group had the necessary expertise. None of the primer sets designed prior to her arrival amplified anything unique to anthrax. In fact, it was against the wishes of Dr. Leighton that Nancy chose to design primers to saspB. He insisted that she should focus on the 'cot', or spore coat, proteins along with Dr. Goldman.

I hired Nancy McKinney because no one else in the group had her set of skills to do both basic and applied research that led to the development of the saspB assay. In addition, she had impeccable quality control and quality assurance skills which we needed to validate the assay and do near neighbor comparison for specificity.

Pascal Longchamp worked on identifying any enzyme activity that might be associated with spores. Stan Goldman's contribution should be evaluated by his notebook, as should all of the listed inventors. I had the original idea to look at receptors or targets that might be present on spores that could be unique and used to detect *B. anthracis* but I did not enable the invention by working in the laboratory or developing the methods to enable the discovery of a specific assay for *B. anthracis*, *B. globigii* and *C. perfringens*.

Once Nancy's initial efforts with saspB paid off, Dr. Leighton claimed only interest in obtaining data for constructing a phylogenetic tree of *Bacillus*. Dr. Goldman participated briefly in analysis of saspB then moved on to other targets. Dr. Longchamp did not participate in analysis of saspB. Only Nancy pursued species specific PCR assays, alone. Drs. Goldman and Longchamp were no longer even employed at LBNL when Nancy developed the anthrax specific primers and probes! And all members of the group, save myself, discouraged Nancy from pursuing this goal claiming it was not possible. She did it on her own, with my encouragement.

I do hope you can see why I have a problem with the inventorship on this CIP.

Sincerely,

Jennie C. Hunter-Cevera

Jennie C. Hunter-Cevera, Ph.D.
President, UMBI

Berkeley Laboratory
Deputy Director for Operations
M/S 50A-4112
Ext. 6120 Fax: 6498

TO: Mina Bissell
Division Director, Life Sciences

FROM: Klaus Berkner
Deputy Directory, Operations

CC: Joseph Cerny
Nancy McKinney
Peter Sandmann (w/o encl.)

SUBJECT: Scientific misconduct charge brought by Terrance Leighton against Nancy McKinney

DATE: July 13, 2000

I am enclosing a copy of a letter dated July 3, 2000 from Peter Sandmann of the law firm of Tesler, Sandmann & Fishman to Laboratory Counsel Glenn Woods. Mr. Sandmann represents UCB Professor Terrance Leighton who is alleging that former LBNL researcher Nancy McKinney engaged in scientific misconduct in regard to an LBNL patent application. Specifically, Professor Leighton alleges that Ms. McKinney's claim as sole inventor on the patent application appears to be an intentional misappropriation of the work of others, and a direct misrepresentation of the contributions of Professor Leighton and others who worked on the grants.

Pursuant to the Laboratory policy on Integrity in Research, I am forwarding this complaint to you for appropriate action. As is provided in 2.05 I of the LBNL Regulations and Procedures Manual, you should appoint one or more individuals to conduct a preliminary inquiry no later than July 28, 2000.

By a copy of this letter I am informing Ms. McKinney and Professor Leighton, through his attorney, that the Laboratory has instituted a review of this matter under its Integrity in Research policy. This policy may be found at www.lbl.gov/LBL-Work/RPM/R2.05.html#RTFToC48 and provides that, although such matters will be treated confidentially, the names of individuals involved will be a matter of record and disclosed to others who have a need to know.

Life Sciences Division
Office of the Division Director

October 12, 2000

Nancy McKinney
CDC, Mailstop C-18
1600 Clifton Road
Atlanta, GA 3033

RE: Preliminary Inquiry Report

Dear Ms. McKinney:

I am enclosing a copy of the report of the Preliminary Inquiry Committee which was appointed to review Professor Leighton's allegation that you had engaged in scientific misconduct.

After considering the report and consulting with Deputy Director Berkner, and after reviewing all of the materials the Preliminary Inquiry Committee considered, I concur in the finding of the Committee that there is no evidence that you intentionally misrepresented or fabricated your efforts to apply for a sole inventorship in the patent in question. Since no scientific misconduct has been identified, it is my decision that a formal investigation is not warranted.

In regard to the Committee's expressed concern about the basis for determining inventions and inventorship in this and other projects related to Life Sciences, I plan to meet with the Patent Manager to review the issues and determine the best course of action.

Sincerely,

Mina J. Bissell, Ph.D.
Director, Life Sciences Division

cc: Professor Terrance Leighton (w/encl.)
Klaus Berkner (w/encl.)
Glenn Woods (w/encl.)
Preliminary Inquiry Committee

Ernest Orlando Lawrence Berkeley National Laboratory One Cyclotron Road, 83-101 Berkeley, California 94720
Tel: 510.486.4365 Fax: 510.486.5586 e-mail: mjbissell@lbl.gov

LAWRENCE BERKELEY NATIONAL LABORATORY

September 15, 2000

MEMORANDUM

TO: Dr. Mina Bissell, Director
Life Sciences Division

From: Preliminary Inquiry Committee

RE: Preliminary Inquiry into Scientific Misconduct allegations brought by Terrance Leighton against Nancy McKinney

The Preliminary Inquiry Committee completed the review of the above allegation. For this task, the committee initially reviewed documents that were provided to us by your office and the office of the Berkeley Lab's council. Subsequently, the committee requested further information from Professor Terrance Leighton and Ms. Nancy McKinney. The committee then conducted interviews with several key participants familiar with the matter.

As a result of the above efforts, the committee concluded that: there is no evidence that Ms. McKinney has intentionally misrepresented or fabricated her efforts to apply for a sole inventorship of the case in question. Hence, no scientific misconduct could be identified.

However, we have grave concerns regarding the basis for determining inventions and inventorship in this project. We recommend the patent office at LBNL re-examine the contributions of all efforts that led to this invention and gather input from neutral experts. Little can be gained from contentious inventorship, which may lead to its invalidation in the long run. In order to avoid such conflicts, it is clear that scientific advice is the only remedy for understanding what constitutes original invention in the framework of rapidly evolving fields. In the future, the patent office may be advised to take advantage of the diverse expertise within Berkeley Lab and seek appropriate input early in the process of filing new patents.

M.H. Barcellos-Hoff, Ph.D.

I. Javandel, Ph.D.

J.F. Cheng, Ph.D.

NANCY MCKINNEY

nmckinney@prodigy.net phone: (650) 747-0273. U.S. Mail: P.O. Box 706, La Honda, CA 94020

EXPERIENCE:

•May 15, 2000- present. Research Scientist, BD Biosciences, Clontech. 1020 East Meadow Circle, Palo Alto, CA 94303. Supervisor: Dr. Steven Hendricks.
Initiated 'real time' PCR R&D effort within Clontech. Evaluated Molecular Beacon and other (proprietary) technologies for 'real time' PCR detection. Developed various TaqMan and other PCR based assays. Performed in-house training and troubleshooting. Established and managed a lab.

•January 30, 2000- April 2001. Research Biologist, GS 12 step 5. CDC/NCID, Bioterrorism Preparedness and Response Program, Rapid Response and Advanced Technology Lab. Supervisor: Dr. Richard Meyer.
Continued the work begun as a Senior Research Fellow in October, 1999. Identified suitable primers and probes for specific detection of anthrax via 'real time' PCR. Tested assays on various instrumentation platforms ABI-7700, ABI-5700, LightCycler, and Cepheid SmartCycler and identified reaction conditions suitable for all instruments. Began evaluating a multiplex format using probes labeled with different fluorophors. Prepared panels of DNA to test primer/probe specificity/'inclusivity', and performed these tests upon each platform. Developed a novel and very rapid method of processing environmental samples for the detection of anthrax spores (for which a patent is being written). Prepared stocks of spores from several virulent anthrax isolates for use in assay development. Performed extensive work in BL-3 level facility for anthrax R&D as well as analysis of 'unknowns'. Developed a novel method to inactivate anthrax spores. Wrote SOPs for spore isolation and for detection of anthrax DNA using the LightCycler, and ABI-7700 instruments. Assembled kits of materials and reagents for multi-center validation of the assays developed.

•October 25, 1999- January 30, 2000. ORISE Senior Research Fellow, CDC/NCID, Bioterrorism Preparedness and Response Program, Rapid Response and Advanced Technology (BRRAT) Lab. Supervisor: Dr. Richard Meyer.
Established diagnostic capability within the BRRAT Lab for rapid, sensitive, and definitive detection of *Bacillus anthracis* in environmental and clinical specimens. Evaluated various anthrax molecular markers as potential targets for 'real time' PCR (TaqMan-type) assays. Designed primers and probes and evaluated those designed by collaborators. Evaluated several strategies for sample preparation. Participated in a team effort to quickly sequence several West Nile Virus isolates using a Beckman CE system. Responded to emergency calls for rapid diagnostics in a timely manner. Learned procedures for proper 'chain-of-custody' handling of evidence and helped maintain a database for the purpose. Worked frequently in BL-3 laboratory preparing specimens, purifying DNA, and preparing spores.

•April 1997- October 15, 1999. Senior Research Associate, Center for Environmental Biotechnology at Lawrence Berkeley National Lab, 1 Cyclotron Road, Berkeley, CA 94720. Supervisor: Jennie Hunter-Cevera.
Designed and developed a *Bacillus anthracis* specific PCR diagnostic assay targeting a genomic marker unique to anthrax. Evaluated the specificity of this assay on clinical and environmental samples. Designed *Bacillus globigii* and *Clostridium perfringens* specific PCR assays. Analyzed DNA from ancient, amber embedded *Bacillus*. Prepared high quality, high molecular weight *Bacillus anthracis* DNA for complete genomic sequencing by TIGR. Analyzed much *Bacillus* DNA sequence. Synthesized primers and probes. Managed lab. Wrote proposals, reports, tutorials, presentations, etc.

•Dec 1991-April 1997. Senior Scientist, Department of Infectious Diseases, Roche Molecular Systems, 1145 Atlantic Ave, Alameda, CA, 94501. Supervisor: Shirley Kwok, Karen Young, Judy Weiss.
1. Part of research team that designed, developed, tested and implemented the Amplicor HIV-I RT-PCR Monitor Assay. Constructed and produced the first internal quantitative RNA standards for the assay, optimized amplification parameters, evaluated sample preparation methods and storage conditions; demonstrated assay utility in clinical trials and various studies.
2. Contributed to the initial understanding of function and utility of AmpliTaq Gold.
3. Developed experimental conditions for multiplex amplification in two different assays: *Mycobacterium tuberculosis* 16S and rpoB genes (for simultaneous *M.tb* detection and Rifampin resistance testing), and *Neisseria gonorrhea* plus *Chlamydia trachomatis*.
4. Contributed to the development of TaqMan, evaluating the (then) 'nascent' technology by designing primers and probes for disease targets and testing them on equipment as it was being developed, in collaboration with (then) PE-Applied Biosystems.

•Sept. 1988 - Dec 1991. Research Associate, Cetus Corporation, formerly 1400 Fifty-third Street, Emeryville, CA, 94608. Supervisor: Shirley Kwok
Pioneered methods for PCR reaction optimization enabling specific target amplification in complex samples. Designed primers and probes, optimized amplification conditions for various target sequences within HTLV and HIV viruses. Conducted feasibility study and testing of the UNG restriction system for PCR carryover prevention.

•Nov 1986 - Aug 1988. Research Assistant, Cetus Corporation. Supervisor: Angela Belt
Purified and confirmed the structure of plasmids and phage for corporate culture collection. Prepared DNA for probes and sequencing. Maintained documentation, cultures and stocks.

•March 1984 - Nov 1985. Staff Research Associate II, UC Berkeley School of Public Health, at Naval Biosciences Lab, Oakland. Supervisor: Dr. Haynes Sheppard.
Screened lambda phage expression vector library of *Leishmania donovani* cDNA with antibodies. Analyzed selected clones via Southern and Northern blot analysis, and fusion proteins via Western blot analysis. Subcloned inserts for sequencing; managed lab.

•Nov 1982 - March 1984. Staff Research Associate I, CVRI, UCSF, Moffitt 1315, 3rd and Parnassis, San Francisco, CA 94143. Supervisor: Dr. Walther Stoeckenius
Freeze-fracture and transmission electron microscopy of *Halobacterium holobium*. Graphics and darkroom work. Managed lab and shared EM/ darkroom facilities.

•May 1982 – Nov 1982. Research Associate, International Plant Research Institute, San Carlos, CA.
Prepared plant virus stocks. Prepared polyclonal antibodies against plant viruses (in rabbits). Developed ELISA assays to detect plant viruses. Began evaluating the efficacy of antiviral compounds vs plant viruses in plant tissue culture.

EDUCATION:

Masters of Science (Plant Pathology/Plant Virology) 1982, U.C. Berkeley, with Chancellor's Fellowship.
Bachelors of Science, 1980, Cal Poly State University, San Luis Obispo, with Highest Honors.

PATENT:

"Species specific identification of spore-producing microbes using the gene sequence of small acid-soluble spore proteins for amplification based diagnostics". Inventor: Nancy McKinney, LBNL. Provisional patent filed by LBNL on 6/8/99, upgraded to regular patent 6/8/00 (still pending).

SECURITY CLEARANCE:

Level 2, Secret, clearance issued August, 2000.

PUBLICATIONS:

N. McKinney, S. Goldman, B. Nelson, G. Long, P. Longchamp and J. Hunter-Cevera. Identification and Validation of a Diagnostic Marker for Anthrax Detection in the Gene Sequence of Endospore Core Protein sasp-B. In preparation.

Nancy McKinney. National Symposium on Medical and Public Health Response to Bioterrorism. SIM News 49, no.3: 138-139. May-June 1999

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P. Palumbo, D. Kwok, S. Waters, Y. Wesley, D. Lewis, N. McKinney, A. Bardeguez, J. Oieske and E.M. Connor. Viral Measurement by PCR Based Assays in HIV Infected Infants. Journal of Pediatrics: 126: 592-95, 1995.

J. Mulder, N. McKinney, C. Christopherson, J.Sninsky, L. Greenfield and S. Kwok. Rapid and Simple PCR Assay for Quantitation of HIV-I RNA in Plasma: Applications to Acute Retroviral Infection. J. Clin. Micro. 37(2): 292-300, 1994.

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REFERENCES available upon request.

LICENSING & COLLBORATION: AVAILABLE TECHNOLOGIES

Assay for Rapid Detection of Anthrax

Ernest Orlando Lawrence Berkeley National Laboratory

APPLICATIONS OF TECHNOLOGY:

- Public health protection
- Clinical detection of anthrax

ADVANTAGES:

- Eliminates false alarms
- Rapid results
- High specificity

ABSTRACT: Berkeley Lab researchers have developed a rapid and accurate assay for detection of anthrax, caused by the bacterium *Bacillus anthracis*. The highly infectious weaponized spores of this bacterium currently top the list of agents recognized as biological threats. Inhalation of anthrax is nearly always fatal, unless quick diagnosis enables immediate antibiotic intervention and vaccination. Hence, rapid and unambiguous molecular diagnostics are needed by clinicians and first responders. N. McKinney and colleagues at Berkeley Lab have developed a rapid assay for unequivocal detection of *B. anthracis*, even in specimens that contain closely-related Bacillus species and other microorganisms. Berkeley Lab seeks industrial partner(s) to develop one or more FDA-approved anthrax detection kits that could immediately identify an accidental or purposeful release into the environment, or detect its presence in clinical specimens.

STATUS: Patent pending/ Available for licensing

PLEASE NOTE: Our Anthrax detection technology has been developed for use in PCR assays and is ready to format to a variety of platforms. We DO NOT have an off-the-shelf product available.

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CONTACT:

Technology Transfer Department
E.O. Lawrence Berkeley National Laboratory
MS 90-1070
Berkeley, CA 94720
(510) 486-6467 FAX: (510) 486-6457
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